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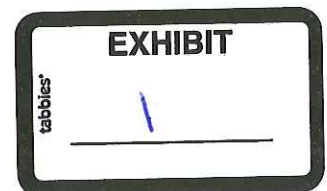


Expert Report of Steven Cohen, M.D.

1. Background and Qualifications:

I am an anesthesiologist and interventional pain management specialist and have been continuously licensed as a physician since 1991, having previous licenses in New York, Pennsylvania and Massachusetts. I currently work and have a license to practice medicine in Maryland. I obtained my medical degree from the Mount Sinai School of Medicine in 1989, completed an internal medicine internship at the Beth Israel Medical Center in New York in 1990, a residency in anesthesiology at Columbia University in 1993, and a pain medicine fellowship at the Massachusetts General Hospital, Harvard Medical School, in 2000. I am board certified by the American Board of Anesthesiology (1994) with added qualifications in Pain Management (2001, 2012).

I am currently the Chief of Pain Medicine, and Director of the Blaustein Pain Treatment Center, at Johns Hopkins School of Medicine, where I also hold joint faculty appointments as a Professor of Anesthesiology & Critical Care Medicine, Neurology, and Physical Medicine & Rehabilitation. I hold additional appointments as a Professor of Anesthesiology and Physical Medicine & Rehabilitation at the Uniformed Services University of the Health Sciences, and serve as Director of Pain Research at Walter Reed National Military Medical Center. Among others, I am or have been a member of the American Academy of Pain Medicine, the American



Pain Society, the American Society of Anesthesiologists, the American Society of Interventional Pain Physicians, and the International Spinal Intervention Society.

I am a retired Colonel in the U.S. Army. During my time as active military, I was deployed four times (2003, 2004 to 2005, and 2007 to 2008) in support of operations in Bosnia, Iraq and Afghanistan. I also served as the Reserve Liaison to the Pain Management Consultants to the U.S. Army and Navy Surgeons General. From 2002 to 2007 I was Chief of Anesthesia & Operative Services at the 4219th Combat Support Hospital in Picatinny Arsenal, New Jersey. From 2007 to 2008 I served as Deputy Commander for the Clinical Services for the 48th Combat Support Hospital at Fort George Meade, Maryland, which is the Chief Medical Office for the base. I served as Chief of Anesthesia & Operative Services at the 48th Combat Support Hospital from 2007 to 2014. I have presented data on pain management in service members to the U.S. Congress, FDA and General Officers. I conducted research that was involved in the passage of the 2008 Military Pain Care Act, and served as an inaugural member of the U.S. Army Medical Advisory Board.

I have over 250 peer-reviewed publications and book chapters on pain in such journals as Lancet, BMJ, Annals of Internal Medicine, JAMA Internal Medicine, New England Journal of Medicine, Anesthesiology, Pain, and Cecil Textbook of Medicine. I am considered a leading expert on low back pain and epidural steroid injections, and was the lead speaker at the 2014 panel the FDA convened on the effectiveness and safety of epidural steroid injections. I have also been consulted by several other similar regulatory agencies in other countries to discuss this topic as well.

My previous awards include the American Society of Regional Anesthesia & Pain Medicine John J. Bonica Award, the American Academy of Pain Medicine Founder's Award, the

American Society of Interventional Pain Physicians Public Service Award, the Donlin M. Long Pain Award, the Teacher and Mentor of the Year Awards from the Johns Hopkins School of Medicine, the Military Health System Distinguished Service Award, the Order of Military Medical Merit, and the Legion of Merit.

A copy of my *curriculum vitae* more fully setting forth my experience and professional accomplishments is attached as Exhibit 1. Any publications I have authored in the previous 10 years are listed on my *curriculum vitae*.

2. List of Cases

A list of cases in which I have testified as an expert in the past four (4) years is as follows:

Clark vs. Brookoff (Plaintiff)-Denver, CO, James Avery
Hinchey vs. Bruning (Plaintiff)-Kansas, Bryson Cloon
Henry vs. Tarozza (Defendant)-Las Vegas, NV, Michael Shannon
Kane vs. Relman (Defendant)-Kansas
Heavner vs. Frederick Memorial (Defendant)-Maryland, Natalie McSherry
Miller vs. Brokaw-Maryland, Michelle Mitchell

3. Facts and Data Considered in Forming My Opinions:

In forming my opinions, I have generally relied on my education, training, experience, and the materials I have reviewed. The following is a brief summary of the facts I rely upon in forming my opinions regarding Box Hill Surgery Center, LLC, Ritu Bhambhani, M.D., LLC, Ritu T. Bhambhani, M.D., LLC (collectively, “Box Hill Defendants” or “Box Hill”), and any agents or employees of the same.

a. Background for Dr. Bhambhani and Box Hill Surgery Center

It is my understanding that Dr. Bhambhani is board certified in anesthesiology and pain medicine. In short, she graduated from medical school in 1994, and then did her post graduate training, including a residency and fellowship in anesthesiology and pain medicine, at the

Exhibit 2

- FDA Form 483 to NECC
- FDA Form 483 to ARL
- Massachusetts BOP/DPH Preliminary Investigative Report
- Report from the Massachusetts Board of Pharmacy's May 2011 inspection of NECC
- NECC Indictment
- Congressional Memo: "FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities?"
- NECC Environmental Monitoring Results
- NECC Cleaning Logs
- NECC Standard Operating Procedures
- Liberty clean room punch list (Ex. 1202)
- Logged Formula Worksheets for the Three Contaminated Lots of MPA
- Daily Fill Logs for the Recalled Lots of MPA
- ARL Testing Results for Three Recalled Lots of MPA
- Video from NECC's Surveillance Cameras
- Video from Inspections of NECC's Facility in December 2012 and July 2014
- Disks containing audio from Barry Cadden's Training for Sales Personnel
- Floorplan Showing the Layout of NECC's Facility
- Scientific Air Analysis Testing Results from 2011 and 2012
- Monthly Cleaning Logs Completed by UniClean Technicians
- Documents regarding a 2012 complaint to NECC from Massachusetts Ear and Eye Institute (the customer complaint)
- Joe Cabaleiro, RPH, New England Compounding Center Indictment, Int' J. Phar Compounding, March- April 2015, at 94.
- ASHP Guidelines (Ex. 1327)
- NECC Quality Assurance Report Cards for 2011 and 2012
- Notes from Keith St. John and Ian Wallis from conversations with NECC's Joe Connolly
- Drug Recall Charts
- NECC Customer List
- FDA Warning Letter to NECC-12/06 (Ex. 1309)
- NECC Letter (1/5/07) to FDA in Response to FDA 2006 Warning Letter (Ex. 1310)
- FDA Letter (10/31/08) to NECC in Response to NECC Response Letter (1/5/07) to FDA 2006 Warning Letter (Ex. 1311)
- FDA Email (7/17/12) Regarding Colorado Cease and Desist Order (5/10/11) and FDA Not Taking Further Action Against NECC at this time (Ex. 1312)
- Emails between NECC and UniClean (Deposition exhibits 422, 424, 426-431)
- Photographs of NECC's standing autoclave
- Photographs of the gaps in ceiling of cleanroom 1
- PCCA formula for compounding MPA
- NECC advertising materials provided to some customers
- New York Times article reporting on several Johnson & Johnson product recalls

- US Compounding, Inc. voluntary recall; 2014-2015 FDA inspections of US Compounding, Inc.; 2012 and 2015 US Compounding, Inc. website printouts
- USP 797
- USP 71
- USP 85
- Expert Report/Declaration of Dr. Philip Austin, Ph.D.
- Deposition of Philip Austin, Ph.D.
- Deposition/Report of Keith St. John
- Deposition/Report of Ian Wallis
- Deposition/Report of Ray Schneider
- Deposition/Report of Sheldon Bradshaw
- Deposition/Reports of Brian Reisetter
- Deposition of William Mixon
- Deposition/Report of Robert Guardino
- Deposition of Stephen O'Neill
- Deposition of Francis McAteer
- Deposition of Michael Cotugno
- Deposition of Edwin Cardona
- Deposition of Ricardo Dos Santos
- Deposition of Edgardo Camacho
- Deposition of Suneela Mistry
- Deposition of Jeffrey Erickson
- Deposition of George Pollick
- Deposition of Robert Kaiser
- Deposition of Michael Debeau
- Deposition of Thomas C. Kupiec
- Deposition of Tommy Means
- Deposition of Samuel Penta
- Depositions of YuZon Wu
- Deposition of Lucy Wilson, M.D.
- Deposition of Joseph Alessandrini, R.Ph.
- Deposition of Mario Giamei
- Deposition of Lisa Cadden
- Deposition of Steven Higgins
- Deposition of Owen Finnegan
- Deposition of Stephen Haynes
- Deposition of Cory Fletcher
- Deposition of Annette Robinson
- Deposition of Belmira Carvalho
- BHSC Responses to Request for Production of Documents (Bates 1-1586) including, among other things, AAAHC certifications and policies and procedures
- Deposition Transcript/Exhibits of Ritu Bhamhani, MD- Box Hill Surgery Center
- Deposition Transcript/Exhibits of Andrew Vickers, RN- Box Hill Surgery Center
- Deposition of Kimberly Brockmeyer

- Deposition of Barbara Wagner
- Expert Report of David Chason, MD
- Expert Report of Lloyd Saberski, MD
- Expert Report of Shmuel Shoham, MD
- Deposition of Lloyd Saberski – Circuit Ct Baltimore County, MD-Consolidated Cases
- Deposition/Report of Lawrence Winikur
- Deposition (Rule 31) of Faye Menter- Cumberland Valley Surgery Center
- Deposition (Rule 31) of Donald Bartnick- Annapolis Surgery Center
- Deposition (Rule 31) of Susan Calhoun-Peninsula Orthopaedics
- Deposition (Rule 31) of Charlotte Rhew-James Davis (Duke) Ambulatory Surgery Center
- Deposition (Rule 31) of Diana Holt-Premier Orthopedics & Sports Medicine-TN
- Deposition (Rule 31) of Laura Ross- Adams, DO-The Ross Center
- Deposition (Rule 31) of Kimberly Mason-University of Tennessee Medical Center
- Deposition (Rule 31) of James Cathey-East Tennessee Children's Hospital
- Deposition (Rule 31) of Noli Dominguez-Central Jersey Orthopedics
- Deposition (Rule 31) of Rhonda Proscia-The Montclair Orthopaedic Group- NJ

- **Angela Farthing, Patient**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-452

- **Linda Torbeck, Patient**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-148

- **Belinda Dreisch, Patient**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center (Bates nos.:1-187)

- **Teresa Davis, Patient**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-86

- **Edna Young, Patient, Deceased Evelyn Bowman, PR of Estate**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-82
- **John Millhausen, Patient, Deceased, Mary Joyce Armetta, PR of Estate**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-26
- **Bahman Kashi, Patient, Deceased, Kiumarc Kashi, PR of Estate**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-24
- **Brenda Rozek, Patient, Deceased, Meghan Handy, Individually and as Surviving Child & PR of Estate**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-39